UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA
ex rel. BROOK JACKSON,

Plaintiff,

- v -

VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC,

Defendants.

CASE NO. 1:21-CV-00008-MJT

ORAL ARGUMENT REQUESTED

ICON PLC'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ICON PLC'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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Defendant ICON plc ("ICON") respectfully submits this reply memorandum in further support of ICON's Motion to Dismiss Count I of the Second Amended Complaint [Dkt. No. 120] pursuant to the Federal Rules of Civil Procedure 9(b) and 12(b)(6). ICON joins and incorporates by reference Defendants Pfizer's and Ventavia's reply memoranda.[1]

PRELIMINARY STATEMENT

Relator's Opposition ("Opposition" or "Opp.") to ICON's Motion to Dismiss the SAC confirms once again the insufficiency of her allegations against ICON. Relator's 32-page Opposition again treats ICON as an afterthought, as has consistently been the case in this litigation. Relator only addresses ICON's arguments in a brief section at the end of her Opposition and does so primarily by restating the same generic and contradictory allegations of trial protocol violations that this Court already found inadequate in dismissing the First Amended Complaint ("FAC"). Indeed, instead of responding to ICON's actual arguments on the insufficiency of the SAC's allegations, Relator's Opposition appears to be more concerned with contesting the effectiveness of the Pfizer vaccine—which is not at issue here.

Most significantly, the Opposition fails to rebut the central argument of ICON's Motion to Dismiss. Namely, despite the Court's dismissal of all claims against ICON in the FAC with prejudice, and despite being given a second chance to attempt to strengthen her pleadings, the SAC adds ***zero*** specific allegations tying ICON to Relator's fraudulent inducement claim under the False Claims Act ("FCA"). Instead, Relator relies on the same allegations as to ICON that this Court

[1] ICON adopts the defined terms set forth in its Motion to Dismiss Relator's Second Amended Complaint and Memorandum of Law in Support [Dkt No. 120] ("ICON's Motion to Dismiss the SAC" or "ICON SAC MTD"). Unless noted otherwise, emphasis is added and internal citations and quotations marks are omitted.

already considered and rejected. Relator's Opposition confirms that she still has not adequately alleged an FCA claim against ICON, for the following reasons.

First, the SAC does not meet the pleading standards of Rule 9(b), as Relator's allegations remain conclusory and speculative.

Second, the SAC fails to allege a fraudulent inducement claim against ICON, as Relator does not (and cannot) properly plead that ICON made—or caused any other Defendant to make—any fraudulent statements or misrepresentations.

Third, the SAC fails to allege scienter as to ICON (or any other Defendant) and, in fact, demonstrates that ICON properly conducted its oversight role and could not have acted with requisite knowledge.

Finally, having now had multiple opportunities to attempt to state a viable claim against ICON, Relator should not be granted leave to amend.

For all of these reasons, the Court should dismiss Count I of the SAC with prejudice.

ARGUMENT

I. THE SECOND AMENDED COMPLAINT FAILS TO SATISFY THE PLEADING STANDARDS OF RULE 9(B)

As set out in ICON's opening brief, the SAC falls far short of meeting the pleading requirements of Federal Rule of Civil Procedure 9(b). (*See* ICON SAC MTD at 5–8). Rather than address ICON's arguments on this point, Relator proposes a new (and incorrect) standard. Specifically, Relator argues that, on a motion to dismiss, Defendants "must show that no facts exist, whether alleged, possibly alleged in an amendment, or discoverable, that provide a basis for either a false claims act cause of action or a retaliation claim." (Opp. at 9). This is simply not a correct statement of law, and in fact ***inverts*** the pleading standards under Rule 9(b), which provides that "a relator must plead 'with particularity' the circumstances surrounding the alleged fraud."

Opinion at *15 (citing Fed. R. Civ. P. 9(b)). These circumstances include "the time, place, and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby." *United States ex rel. Willard* v. *Humana Health Plan,* 336 F.3d 375, 384 (5th Cir. 2003).[2]

Elsewhere in the Opposition, Relator appears to concede that her pleading must satisfy this heightened standard, but argues that she need not "describe all actions, dates, participants and other details of the alleged fraud at the pleading stage." (Opp. at 8–9) (citing *United States ex rel. Bechtold* v. *Asfora,* 2020 WL 5547920, at 2 (D.S.D. Sept. 16, 2020)). While Relator of course need not put forward "all" details of the alleged fraud now, she must still plead at least ***some*** details with specificity and particularity. Rule 9(b) requires that a complaint allege "as to ***each individual defendant*** the nature of the fraud, ***some details,*** [and] a brief sketch of how the fraudulent scheme operated, when and where it occurred, and the participants." *Hernandez* v. *CIBA-GEIGY Corp. USA*, 2000 WL 33187524, at *5 (S.D. Tex. Oct. 17, 2000) (quoting *Askanase* v. *Fatjo*, 148 F.R.D. 570, 574 (S.D. Tex. 1993)). But Relator does not come close to satisfying Rule 9(b)'s pleading standards as to each Defendant, and certainly not as to ICON. The meager allegations of misconduct as to ICON specifically remain generic, conclusory, or speculative.

Relator argues in her Opposition that ICON was an "instrument[] through which [the alleged] fraud was perpetrated." (Opp. at 29). But the SAC does not reference ICON at all in the

[2] Relator mischaracterizes the holdings of *Clark* v. *Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986) and *United States ex rel. Riley* v. *St. Luke's Episcopal Hosp.* 355 F.3d 370, 376 (5th Cir. 2004)—the decisions she relies on for this bold misreading of the law—which nowhere suggest that Defendants have the burden to disprove Relator's assertions at the motion to dismiss stage. At most, these decisions caution against using a motion dismiss as a backdoor summary judgment motion to rule on the merits. *See Clark*, 794 F.2d at 970; *Riley*, 355 F.3d at 376. Indeed, the court in *Riley* confirmed the heightened pleading requirements that Relator must meet to prevail on this motion. *Riley*, 355 F.3d at 381 ("We remind the district court, however, of the central importance of Rule 9(b) in regard to allegations of fraud[.]").

20 paragraphs that purport to allege fraudulent inducement, nor does it plead any new facts as to ICON, other than one conclusory throwaway line.[3] Relator's Opposition does not change or even address this pleading deficiency. It merely regurgitates allegations from Relator's dismissed-with-prejudice complaint, including allegations that ICON ignored red flags of trial protocol violations, "failed to remove compromised clinical trial data," and failed to report adverse events, furnish reports, or follow up on outstanding inquiries. (Opp. at 29–30). Once again, Relator does not explain with particularity how these alleged protocol violations constituted false statements to the Government and offers no specific details of the alleged red flags or falsified data—the necessary "who, what, when, where, and how." *See Willard*, 336 F.3d at 384–85 (dismissing fraudulent inducement claim where complaint "does not allege who was involved in the negotiations, or where or when the negotiations took place, or . . . what was said before, during or after the contract negotiations").

Relator's Opposition also fails to address, and thus concedes (*see supra* n.3), several arguments from Defendants' Motions to Dismiss. The Opposition fails to address ICON's argument that the SAC's supporting exhibits demonstrate that ICON did not ignore issues with the clinical trial, but instead actively followed up and worked with Ventavia personnel to correct them, plainly contradicting the generic allegations otherwise in the SAC. (*See* ICON SAC MTD at 7);

[3] The SAC's only revision that specifically references ICON alleges "demonstrated reckless monitoring by ICON" (SAC ¶ 163), an allegation wholly lacking in necessary detail. Otherwise, the SAC merely adds conclusory allegations against "Defendants" as a whole, without explaining the alleged involvement of ***each*** Defendant or the details of ***each*** Defendant's purported conduct. (*See, e.g.*, SAC ¶¶ 348–54). This generic group pleading, without specific allegations as to each Defendant falls far short of the requirements of Rule 9(b). (*See* ICON SAC MTD at 6-8 (citing *In re Parkcentral Global Litigation*, 884 F. Supp. 2d 464, 470-71 (N.D. Tex. 2012))). Relator's Opposition fails to address this argument and thus concedes it. *See Satanic Temple, Inc.* v. *Young*, 2023 WL 43117185, at *5 (S.D. Tex. July 3, 2023) ("Failure to brief a point forfeits opposition to that point."), *aff'd*, 2023 WL 9107299 (5th Cir. 2023); *Safe Home Sec., Inc.* v. *Philadelphia Indem. Ins. Co.*, 581 F. Supp. 3d 794, 798 (N.D. Tex. 2021) ("Generally, the failure to respond to arguments constitutes abandonment or waiver of the issue . . . . Plaintiffs, therefore, waived this objection and legal argument by not including it in their response to Defendant's Motion.").

see also Riley, 355 F.3d at 377 ("If an allegation is contradicted by the contents of an exhibit attached to the pleading, then indeed the exhibit and not the allegation controls.").

Relator's allegations regarding ICON are, at best, accusations regarding regulatory violations and thus cannot constitute the basis of fraud. As this Court explained when previously denying leave to amend: "Pleading additional regulatory violations will not remedy [Relator's] inability to plead that Defendants made false statements or engaged in a fraudulent course of conduct." The SAC does not even plead ***additional*** regulatory violations regarding ICON, but instead merely repeats the same insufficient allegations that this Court has already dismissed.

II. THE SECOND AMENDED COMPLAINT FAILS TO ALLEGE FACTS SUPPORTING A FRAUDULENT INDUCEMENT CLAIM AGAINST ICON

The SAC summarily claims that Defendants fraudulently induced the U.S. government to issue an EUA in order to develop Pfizer's COVID-19 vaccine, violating the FCA. (SAC ¶¶ 309, 347–57). But, as established in Defendants' opening briefs, the SAC fails to sufficiently allege that ICON, or any other Defendant, made any false claims or representations that fraudulently induced the government to enter into a contract. *See* Pfizer's Motion to Dismiss Relator's Second Amended Complaint and Memorandum of Law in Support [Dkt. No. 119] at 13; Ventavia's Motion to Dismiss Relator's Second Amended Complaint and Brief in Support [Dkt. No. 121] at 2, 4; ICON SAC MTD at 8. Nothing in the Opposition changes this conclusion.

Relator's SAC simply makes ***no new allegations against ICON*** concerning fraudulent inducement. (*See* ICON SAC MTD at 7-8). As discussed *supra*, it merely regurgitates allegations from Relator's previous dismissed-with-prejudice FAC under the cover of a fraudulent inducement theory. Relator declares in her Opposition—for the first time—that "Pfizer submitted claims for payment that were false based upon the upstream fraud on the FDA, and both Ventavia and Icon were the instruments through which that fraud was perpetrated." (Opp. at 29). However, she

offers no factual allegations whatsoever as to ICON's supposed role as an "instrument," but rather falls back on unsupported allegations that ICON's purported non-compliance with protocols and regulations rendered its prior certification of Form FDA-1572 to be a false statement. (SAC ¶¶ 172, 323). This claim does not even pass muster under the more liberal pleading standard of Rule 8(a)(2), let alone the exacting standard of Rule 9(b), for three primary reasons.

First, neither the SAC nor the Opposition allege a connection between the supposed "contract" Defendants allegedly fraudulently induced (Pfizer's application for the EUA) and ICON's supposed false statement (the Form FDA-1572). Nowhere does Relator allege that the Form FDA-1572 was required for or material to Pfizer's EUA application. The SAC instead merely alleges that FDA clinical trial sponsors, such as Pfizer, must collect these forms from contract investigators, such as ICON. (*See* ICON SAC MTD at 11).

The Court should not credit Relator's contention—made for the first time in her Opposition—that Form FDA-1572 "was a document [ICON] submitted ***to the FDA*** as part of Pfizer's overall EUA application." (Opp. at 30) (emphasis added). "[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Roebuck* v. *Dothan Sec., Inc.*, 515 F. App'x 275, 280 (5th Cir. 2013). Here, Relator has never pleaded when, whether, by whom, or to whom at the FDA the Form was purportedly submitted by ICON, alleging only that ICON provided the Form to Pfizer. (*Compare* Opp. at 30 *with* SAC ¶¶ 56, 57, 172, 323). Accordingly, this new and unsupported assertion is not properly before this Court.

Second, as this Court previously recognized—and as remains the case in the SAC—Relator does not allege any specifics about the supposed false representations made by ICON in the Form FDA-1572. *See* Opinion at *4 n.7. Indeed, Relator does not allege specifics about ***any***

representations made in the Form FDA-1572, only attaching a blank example form to the SAC (SAC, Ex. 5) rather than the form that ICON actually submitted. (*See* ICON SAC MTD at 10).

Third, Relator alleges that ICON ignored or violated trial protocols ***after*** the contract with the government was entered into by Pfizer. (SAC ¶¶ 117, Opp. at 29–30). This is insufficient. (*See* ICON SAC MTD at 9-10). Without plausible allegations that ICON intended from the start to violate trial protocols when the contracts were entered into, these allegations cannot support a fraudulent inducement theory. *See, e.g.*, *United States ex rel. Dekort* v. *Integrated Coast Guard Sys.*,705 F. Supp. 2d 519, 537 (N.D. Tex. 2010) (finding fraudulent inducement theory implausible where "the actions described by Relator occurred ***after*** the contract had been awarded" (emphasis in original)); *see also United States ex rel. Guzder* v. *MKM Engineers Inc.*, 2009 WL 10697658, at *3 (S.D. Tex. May 1, 2009) (FCA fraudulent inducement theory required "more than the allegation that a defendant has accepted federal funds while in violation of certain funding program requirements"). Relator unsurprisingly ignores this fatal pleading failure.

III. THE SECOND AMENDED COMPLAINT FAILS TO ADEQUATELY ALLEGE THAT DEFENDANTS ACTED WITH THE REQUISITE SCIENTER

As explained in ICON's opening brief, Relator fails to allege scienter as to ICON (or any other Defendant). ICON SAC MTD at 11–13. In fact, the SAC suggests that knowledge of trial protocol violations was in fact ***hidden*** from ICON, attaches exhibits that directly contradict any suggestion that ICON had "constructive knowledge" of the supposed violations, and ultimately fails to establish that ICON had actual knowledge of false claims made to the government. *Id.*

In her Opposition, Relator claims that ICON "at minimum" acted with reckless disregard or with "deliberate ignorance, given the numerous red flags evident during the clinical trials . . . . Icon suggests that the wrongdoing was hidden from it, but Icon had access to all trial data from clinical trial participants' source documents." Opp. at 31. This bare assertion is contradicted by

Relator's SAC, which repeatedly suggests that ICON could ***not*** have acted with knowledge, because the purported violations of regulations and procedures were alleged to have been ***hidden from*** ICON. (*See* ICON SAC MTD at 12). For example, the SAC reads: "Ventavia did not report [an] issue to Pfizer or Icon, instead placing Notes to File ('NTFs') in patients' charts . . . . ***The NTFs are not viewable by Pfizer or Icon until the end of the clinical trial***" (SAC ¶¶ 182–83), "[t]he NTF ***were not accessible*** to Pfizer or Icon until the end of the clinical trial which was at least two years out . . ." (*Id*. ¶ 191), and "Ventavia was required to scan or enter all data from clinical trial participants' source documents into [the database], so that it could be passed on to Icon and Pfizer . . . .[U]ploading fell behind schedule." (*Id*. ¶ 269). The exhibits to the SAC also refute any suggestion that ICON failed to make inquiries or that it "buried its head in the sand." *See supra* Part I. The exhibits show ICON making specific inquiries to Ventavia regarding the trials it was conducting. (*See* ICON SAC MTD at 12). Read holistically, the SAC alleges, at the very most, the sort of "[i]nnocent mistakes, mere negligence, or even gross negligence" that courts have found "not actionable" under the FCA. *United States ex rel. Longhi* v. *Lithium Power Techs., Inc.*, 513 F. Supp. 2d 866, 875–76 (S.D. Tex. 2007).

Even if Relator had adequately established that ICON had knowledge of alleged trial protocol violations, that is not the relevant inquiry. What is actually at issue in this *qui tam* action is whether ICON acted with scienter as to the ***material falsity of claims or statements made to the government***. *See United States ex rel. Steury* v. *Cardinal Health, Inc.*, 2011 WL 13266915, at *5 (S.D. Tex. Aug. 29, 2011), *report and recommendation adopted*, 2011 WL 13266916 (S.D. Tex. Sept. 27, 2011) ("[B]ecause the FCA is not a general 'enforcement device' for federal contracts, merely selling defective goods to the government is not enough to create liability[.] . . . Instead, a plaintiff must show that a contractor actually made a false statement to secure payment for the

goods."). Relator comes nowhere close to alleging this. (*See* ICON SAC MTD at 10). Nor could she, since ICON never submitted a claim for payment to the government. Even if this Court were to credit the SAC's alleged trial errors and mistakes, these do not constitute a knowing violation, because courts are clear that under the FCA "a lie is actionable," but a mere "error" is not. *United States ex rel. Johnson* v. *Kaner Med. Grp., P.A.*, 641 F. App'x 391, 394 (5th Cir. 2016).

IV. LEAVE TO AMEND SHOULD BE DENIED

Leave to amend is not warranted. While Rule 15(a)(2) provides that courts should "freely give" leave to amend "when justice so requires," "leave to amend is by no means automatic." *Halbert* v. *City of Sherman, Tex.*, 33 F.3d 526, 529 (5th Cir. 1994). Relator requests further leave to amend "in the event that the Court find[s] any deficiencies" in the SAC (Opp. at 32), but the SAC fails to cure deficiencies already identified by this Court (Opinion at *24), and Relator does not explain how she would cure these deficiencies through further amendment. Relator's request should be denied for three primary reasons.

First, "leave to amend properly may be denied when the party seeking leave has repeatedly failed to cure deficiencies by amendments previously allowed." *Willard*, 336 F.3d at 387. Here, Relator has had nearly nine months to amend her Complaint with the benefit of the guidance previously provided by this Court. But rather than cure the FAC's deficiencies, the SAC doubles down on them. *See supra* Part II. Indeed, a dispositive defect of Relator's pleading—that it pleads alleged regulatory violations, not false claims—remains the same.[4] Relator should not be granted yet another bite at the apple. *See St. Germain* v. *Howard*, 556 F.3d 261, 264 (5th Cir. 2009)

[4] *See* Opinion at *44 ("Pleading additional regulatory violations will not remedy [Relator's] inability to plead that Defendants made false statements or engaged in a fraudulent course of conduct").

(upholding denial of a motion for leave after plaintiff had multiple opportunities to state a case); *Herrmann Holdings Ltd.* v. *Lucent Techs., Inc.*, 302 F.3d 552, 566–67 (5th Cir.2002) (same).

Second, the SAC fails to suggest how an amendment would cure Relator's ongoing pleading deficiencies, including Relator's inability to demonstrate false statements or a fraudulent course of conduct by Defendants and materiality (Opinion at *24), much less how her claims would satisfy Rule 9(b). Relator's failure to specify "how amendment would cure the fundamental deficiencies in [her] pleading" is yet another reason to deny her request. *Chuttoo* v. *Horton*, 627 F. Supp. 3d 655, 682 (E.D. Tex. 2022) (denying leave to amend as futile because plaintiff did not "offer any additional facts that he would, or could" add to his complaint to address its deficiencies).

Third, after Relator's multiple attempts to state a viable claim against ICON, it is now clear that Relator "has pled . . . her best case, and there are no additional facts that could be alleged in a second amended complaint that could not have been alleged in the [original complaint]." *BG Gulf Coast LNG, LLC* v. *Sabine-Neches Navigation Dist. of Jefferson Cnty., Texas*, 587 F. Supp. 3d 508, 527 (E.D. Tex. 2022) (Truncale, J.); *see also Ariyan, Inc.* v. *Sewerage & Water Bd. of New Orleans*, 29 F.4th 226, 232 (5th Cir. 2022) (affirming denial of leave to amend where "pleadings [were] found to be deficient" and "Plaintiffs did not specify which amendments they wished to make, or attach an amended pleading"). Accordingly, Relator's request should also be denied on the grounds of futility.

CONCLUSION

For the foregoing reasons, in addition to those set forth in the reply briefs filed by Pfizer and Ventavia, ICON respectfully requests that the Court dismiss the claims asserted against ICON in their entirety with prejudice.

Date: January 19, 2024

Respectfully Submitted,

/s/ Scott L. Davis

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on January 19, 2024, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Scott L. Davis
Scott L. Davis